Guidance and Advice
K12
Institutional Clinical Oncology Research Career Development Program

I. IMPORTANT ANNOUNCEMENTS:

The guidance and advice provided below are derived from the National Cancer Institute (NCI) Program Announcement (title: Clinical Oncology Research Career Development Program; number: PAR–00-63) issued in the NIH Guide on February 17, 2000. You can access this announcement directly by "clicking on" the following NIH website address: http://grants.nih.gov/grants/guide/pa-files/PAR-00-063.html. After consulting the offical announcement, the information and clarifications provided below together with the Form PHS 398 application kit should be all that you need to prepare an application for the Institutional Clinical Oncology Research Career Development Program or **K12.**

II. BACKGROUND:

The purpose of the National Cancer Institute (NCI) Clinical Oncology Career Development Program is to increase the number of medical doctors and doctorally degreed Oncology Registered Nurses who are motivated and properly trained to: (1) communicate and collaborate with basic/behavioral research scientists in order to expedite the translation of basic/behavioral information into **patient-oriented research**; (2) perform independent clinical research that develops and tests rational scientific hypotheses based on fundamental and clinical research findings with the potential for improving the medical care of cancer patients; and (3) design and test innovative clinical protocols and manage **all phases (i.e., pilot/Phase I, Phase II, Phase III) of clinical trials research**. **For the purposes of this award patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator *directly interacts with human subjects*. This area of research includes: 1)mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; and 4) the development of new technologies**. The distinguishing features of this Program are that a Program Leader in the institution together with an Advisory Committee selects the candidates and oversees the course of their training; and that Candidates are likely to have more than one mentor to achieve their training objectives in the basic sciences and the many disciplines critical to the clinical sciences.

In 1991 the National Cancer Institute (NCI) recognized the need for establishing formal training programs that would prepare the next generation of clinical scientists to participate more effectively in translational clinical research, which the NCI simply defines as the movement of discoveries in the laboratory into patient research settings or the reverse process of taking observations in the clinic back into a laboratory research setting. The NCI abandoned its previous strategy of expecting M.D./Ph.D.s to do this alone and embarked on a pilot program initiative that would prepare clinical oncologists to be effective scientific partners with basic scientists in the translational research process. These well-trained clinical oncologist scientists would be expected to communicate, interact and collaborate with basic/behavioral scientists in the design and implementation of clinical trials that were hypothesis driven and based on an understanding of biological mechanisms. This pilot program initiative, announced in 1991 through RFA CA-91-32 and again in 1997 through RFA CA-97-008, was founded on the following principles: (1) unlike career awards to individuals, these would be awards to institutions and the institution would appoint individuals to a formal training program; (2) rather than having a single mentor, the individuals on the program would likely have more than one mentor as they are exposed to the basic sciences and to the many disciplines critical to the clinical sciences; (3) the program would provide individuals with all of the information and training needed to design, implement and manage all phases of clinical trials research. The success of these pilot initiatives resulted in the NCI converting this Program from one that was driven by dollar set-asides and RFAs to one that is investigator-initiated and regularly available to the clinical oncology research community.

The NCI anticipates that the availability of "multidisciplinary" research environments during the formative years of clinical research training will promote the team approaches that will be necessary for optimizing patient-oriented translational research. This Program focuses strictly on the preparation of clinical oncologists for research careers and relies on the institution to select and train candidates. "Click on" *Clinical Scientists, Patient-Oriented Research* in the margin of this page to explore other opportunities for those who are clinically educated to pursue careers in clinical research.

III. ELIGIBILITY:

1. **Institution:** Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applicant organizations should have well established research programs with adequate peer-reviewed grant support and highly qualified faculty in clinical, behavioral and basic science departments.

2. **Program Leader/Principal Investigator:** The Program Leader must be an established investigator in patient-oriented research and able to provide both administrative and scientific leadership to the Program. Minorities, women and individuals with disabilities are encouraged to apply.

3. **Clinician Candidates:** All candidates **must** currently be physicians holding the M.D. or D.O. degrees, or be doctorally prepared oncology registered nurses and **must** have completed their clinical training (i.e., completed residency and are board eligible). Candidates **must be able to** spend a minimum of 75 percent of a full-time professional effort conducting research and research career development including taking courses during the period of the award.
   All clinician candidates **must** be U.S. citizens or non-citizen nationals, or must be lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some verification of legal admission as a permanent resident of the U.S. Non-citizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S.; they usually are born in the lands that are not states, but under U.S. sovereignty, jurisdiction or administration. **Foreign nationals and individuals on temporary or student visas are NOT ELIGIBLE.**

   Clinician candidates who were former principal investigators on NIH Small Grants (i.e., R03s) or Exploratory/Developmental Grants (i.e., R21s) remain ELIGIBLE. However, former principal investigators on NIH research project grants (i.e., R01s), FIRST Awards (i.e., R29s), comparable career development awards (e.g., K01, K07, K08, K23), sub-projects on Program Projects (i.e., P01s) or center grants (i.e., P50s) and equivalent are **NOT ELIGIBLE** for appointment to a K12 grant.

IV. MECHANISM OF SUPPORT:

Clinical Oncology Research Career Development Programs use the **K12** grant mechanism and provide up to **five years** of support. Planning, direction and execution of the Program is the responsibility of the Program Leader and the Advisory Committee on behalf of the institution. **K12s are renewable.**
K12 awards are administered under NIH grants policy. However, K12s are not subject to "just-in-time" application procedures or to the Streamlined Noncompeting Application Process (SNAP). Expanded Authorities are in place, except that carry over of funds from one fiscal year to the next requires NCI approval.

V. ALLOWABLE COSTS:

The NCI Clinical Oncology Research Career Development Program or **K12** provides for the following costs:

1. **Direct cost cap:** Total direct costs cannot exceed $700,000 per annum without specific permission from the NCI. However, because NIH policy requires that any application greater than $500,000 per year in direct costs receive permission from the funding institute before it can be

accepted for review, any applicant planning to request more than $500,000 must submit the K12 application with a cover letter identifying the official by name who granted permission.

2. **Salary:** Clinician trainees may be provided salary up to $75,000 each year, plus fringe benefits. The actual salary **must** be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other members of equivalent qualifications, rank and responsibilities in the department concerned.
   Salary for the Program Leader/ Principal Investigator and participating faculty is **NOT** allowed.
   The institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which the funds are derived. Because the salary amount is based on a full-time institutional salary, no other PHS funds may be used for salary supplementation. Institutional supplementation of salary must NOT require extra duties or responsibilities that would interfere with the trainees' time commitment to research and career development. Under expanded authorities, institutions may rebudget funds within the total costs to cover salaries consistent with the institution's salary scale.

3. **Research and Development Support:** Up to $30,000 in direct costs per trainee per year can be provided for the following types of expenses: (a) research expenses, such as supplies, equipment and technical personnel; (b) tuition, fees and books related to career development; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time. These costs must be **specifically and directly** related to an individual trainee's **research** activities. They cannot be pooled and used for advertising, recruiting or other purposes unrelated or indirectly related to the research activities of individual trainees.

4. **Ancillary Personnel Support**: Salaries for mentors, secretaries, administrative assistants and other ancillary personnel are **NOT** allowed.

5. **Facilities and Administrative Costs (formerly called indirect costs) :** These will be reimbursed at 8 percent of modified total direct costs or the actual cost rate, which ever is less.

6. The K12 grant, as administered by the NCI is not subject to the Streamlined Noncompeting Application Process (SNAP). In general, this means that all reporting of budgetary information and program progress are provided in greater detail in an annual progress report. While the K12 is subject to Expanded Authorities, the one exception to this is that carry over of funds from one fiscal year to the next must receive approval by NCI Grants Administration Staff (see XI. INQUIRIES).

7. **Other General Policies Related to Costs:**
   a. The NCI does not allow **grant related income** (i.e., fees) from clinical practice, professional consultation, or other comparable activities required by the research provisions of this award to be retained by the principal investigator or the candidate. These fees must be assigned to the grantee institution for the disposition by one of several approved NIH methods.
   b. **Carryover of unobligated balances** into a future year of the grant may be permitted under exceptional circumstances. Requests for approval of carryover must be made directly to NCI program staff. The unobligated balance that can be carried over is subject to the current NIH limit.
   c. **Funds freed up** from other NCI-supported research or training grants as a result of a K12 award may not be rebudgeted by the institution.
   d. Prior approval for candidates to **travel to a foreign research environment** as part of the training is required only if the stay exceeds three months.
   e. A trainee may have up to a 12 month **leave of absence** without award support with prior written approval from the NCI.
   f. A **K12** grant **cannot** be transferred to another institution.

For appropriate advice and specific instruction regarding the above and other budgetary and administrative policies that you must follow in managing this award, please refer to section **XI. INQUIRIES.**

VI. SPECIAL PROVISIONS AND REQUIREMENTS:

1. **Salary and Research Development Costs:** The NCI establishes the upper limits of $75,000 for salary support plus fringe benefits and the $30,000 for research development support. Other institutes and centers at the NIH implement different dollar levels for these categories at their discretion.

2. The NCI will **NOT** consider a **change of institution** of a **K12.**

3. The Program Director **must use an Advisory Committee** to provide an oversight function and annual evaluation of the clinical research development program as a whole. Clinical, basic and behavioral science departments, and oncology nursing departments participating in this program should be represented on the committee by clinical investigators from the various oncology disciplines such as medical oncology, surgical oncology, radiation oncology, oncology nursing and other oncology specialties as well as by basic and behavioral research investigators. The committee's **responsibilities might include:** selecting physician and oncology nurse candidates, assigning preceptors, approving each trainee's clinical research development plan, evaluating each candidate's progress, and monitoring overall effectiveness of the program. A detailed description should be provided of the committee's composition, function, and frequency of meetings. **A summary report of the actions of the committee meetings must be provided with the annual progress report of the grant**. Plans for an annual evaluation of the program by the Advisory Committee should be described.

4. The clinical oncology research career development programs must involve staff and clinical candidates representing **at least two clinical oncology disciplines** such as medical, surgical, radiation, pediatric, gynecologic oncology and oncology nursing.

5. The program **must** provide clinician trainees with the patient-oriented research skills that deal directly with aspects of cancer detection, diagnosis, prognosis, or treatment of cancer patients; and should provide the skills necessary for translating basic/ behavioral cancer research results into clinical experiments, procedures, and trials directly involving cancer patients in a clinical environment. **It will not be sufficient within the scope of this initiative to use human cells and other clinical materials or animals in an isolated basic laboratory setting as the total research development program.** Basic laboratory/behavioral research experience is essential, but it must be properly integrated with patient-oriented clinical research, thereby affording the trainee actual experience in the application of their own basic research to clinical research.

6. The proposed program should have the flexibility to accommodate clinician trainees with different levels of basic and clinical research competence.

7. Appointments of clinical candidates to the program should be for a **minimum of two years.** As long as a **K12** grant has been renewed, individual candidates **can be supported for up to seven years.**

8. The Program should include Core Requirements that each candidate is expected to complete before meeting the Program's training objectives. These requirements should include the following:
    - A *didactic* core component (e.g., formal courses in clinical trial design, biostatistics, informed consent, Institutional Review Boards; lecture series, seminars, and journal clubs) based on the experience and needs of each candidate. In those institutions with a Clinical Research Curriculum (K30) Award, the didactic component should link with and incorporate the new didactic programs developed through the K30 award.

- A *clinical research* core component the provides "hands on" experience (e.g., protocol development; preparation of IRB applications; clinical trials management including patient accrual, analysis of outcomes) in all aspects of clinical trials.
- A *basic research* core component that adequately prepares the trainee for communication, coordination, and collaboration of clinical research activities with basic scientists; ideally this would be linked to the core clinical research component.

The expectation of the NCI is that candidates entering the Program with different backgrounds initially will satisfy many of the Core Requirements and that they will be provided with the additional didactic and research experience over different periods of time in order to fully meet the objectives of the Program.

9. A minimum of **75 percent effort** must be devoted to the **K12** program. The remaining 25 percent can be divided among other clinical and teaching activities consistent with the program goals, i.e., the candidate's development as a clinical oncology researcher.

10. The institution must have a **well-established research** and clinical career development program, and **faculty** qualified in clinical research with an emphasis on patient-oriented research. The research environment should be one in which there are active basic/behavioral/clinical research collaborations that exemplify a dynamic two-way exchange of information and ideas between laboratory and clinical scientists. The research environment should also promote rapid translation of basic/behavioral/oncology research into clinical testing as well as stimulate new ideas and laboratory experiments, based on clinical observations and testing results.

11. The institution must demonstrate a commitment to the development of trainees as productive, independent clinician investigators.

12. Where there already exists an active institutional (T32) National Research Service Award (NRSA) supporting a surgical or other clinical oncology research training program, the applicant **must** address the relationship between the existing T32 and proposed K12 programs. If there is significant overlap in the programs, the T32 award can be merged into the K12 program or modified to remove areas of substantial overlap.

13. **Evaluation**: In carrying out its stewardship of human resources-related programs, the NCI or the NIH may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients of support from this grant may be contacted after completion of the award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities and other information helpful in evaluating the impact of this program.

VII. APPLICATION PROCEDURES:

SUBMISSION, REVIEW AND AWARD OF **COMPETING APPLICATIONS**

A. Application Receipt, Review and Award Dates:

There is one receipt date per year for K12 applications. This is June 1 for all new, renewal, supplemental and amended applications. Initial peer review of the application for scientific merit by an NCI initial review group is usually completed in October. Review by the National Cancer Advisory Board is usually completed in January. The earliest possible award date is April 1.

B. Where to send the application:

An **original and three copies** of the application should be submitted to the Center for Scientific Review (CSR), NIH, according to the instructions in the PHS Form 398 (rev. 4/98 and subsequent revisions) to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040-MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (For express/courier service)

To expedite review the review process, **two additional copies** should be sent to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard, Room 8062
MSC/8329
Bethesda, MD 20892-8329
Rockville, MD 20852 (express/courier service);

C. Format for Submitting the Application:

Applications for the Clinical Oncology Research Career Development Program or K12 are to be submitted on the grant application Form PHS 398 (last revised 4/98) **using the modified instructions below**. You can obtain the application forms directly by "clicking on" the following NIH website address: http://grants.nih.gov/grants/funding/phs398/phs398.html.Forms are also available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, FAX: (301) 480-0525, Email: GrantsInfo@ nih.gov.

Note of caution:

Type density and size for the entire application must conform to the instructions on Page 6 of the general instructions for the Form PHS 398. If they do not, the application could be returned to you by CSR without review.

General advice in Preparing a K12:

It is highly recommended that you make regular reference to the Review Criteria under section **VIII. REVIEW PROCEDURE AND CRITERIA** during the preparation of your application. The success of your application in addressing these criteria will determine its competitiveness for funding.

Modified Instructions for Preparation of a K12 Application:

The instructions in the Form PHS 398 application **do not fully apply** to the special needs of this institutional career development grant. This includes the "Just-In-Time" instructions for the submission of detailed budgets. **Detailed budgets must be provided.** Therefore, **please follow the modified instructions below** in preparing an application for the Clinical Oncology Research Career Development Program (**K12**). These instructions have been adapted to accommodate the Form PHS 398 and the special needs of the K12 grant:

1. **Face Page**: Use page AA of the Form PHS 398. On Line 1 include the title that best represents the nature of your training program. On line 2, provide the number starting with PAR, and title, "Clinical Oncology Research Career Development Program," of the NCI Program Announcement. The Program Leader will be the principal investigator (P.I.) of the grant application.

2. **The Description/Performance Site(s)/Key personnel** (page BB of the Form PHS 398**)**: Complete as directed in the PHS 398, page IV-2. This should include the Principal Investigator, Advisory Committee members, mentors participating in the Program, and other faculty

participating in the program. Please make sure that you denote each individuals degree and department affiliation (or equivalent).

3. **Table of Contents** to be organized as follows:

Content Page Number

a. Face Page
b. Description/Key personnel
c. Table of Contents
d. Statement of Commitment
e. Detailed Budget Page for First Year
f. Budget for Entire Proposed Period of Support
g. Biographical Sketches (not to exceed 2 pages per individual)
    - Biographical sketch of the Program Leader
    - Biographical sketches of the Advisory Committee
    - Biographical sketches of Mentors
    - Biographical sketches of Other Faculty
    - Biographical sketches of Trainees (if available)
h. Other Support of the Principal Investigator and the Mentors that is specifically relevant to the purpose and objectives of this Career Development Program
i. Career Development/Training Plan (**May exceed 25 pages; tables should be included in the text, not as appendices):**
    i. Introduction to **Revised Application** (not to exceed 3 pages)
    ii. Purpose and Objectives
    iii. Description of Core Requirements
    iv. Research Base/Resources and Facilities/Mentors
    v. Program Management
        - Program Leader
        - Recruitment Strategies
        - Advisory Committee
        - Individual Training Plans
j. Summary Information on Program (We have created suggested tabular formats for your convenience. "Click on" TABLES (Word for Windows) or TABLES (Word Perfect), which ever you prefer, to download this information.
k. Human Subjects
l. Vertebrate Animals
m. Checklist
n. Appendices

4. **Statement of Commitment**: This statement should guarantee that all candidates participating in this Program will commit 75% of a full-time professional effort to research and research career development.

5. **Detailed Budget for the First Year**: Use Form Page 4 (or DD) of the Form PHS 398 and provide the salary and fringe benefits, supplies, travel, etc., for each trainee, either by name or by position (i.e., position 1, position 2 etc.) if the position is not filled. Note that there is an upper level of salary of $75,000 plus fringe benefits and an upper limit for other costs of $30,000 per trainee.

6. **Budget for the Entire Proposed Period of Support**: Follow directions as provided in the Form PHS 398.

7. **Biographical Sketches**: Provide biographical sketches using page FF provided in the PHS 398 application kit. Divide into four sections: (1) Principal Investigator; (2) Advisory Committee; (3) Mentors; (4) Other Faculty; and (5) Trainees (when available)

8. **Career Development/Training Plan:**

a. Purpose and Objectives: Briefly describe the background, purpose, and objectives of this career development program. This description should include **two or more oncology disciplines** being trained in the program and a discussion of the strategies to be used to ensure that the representation in each discipline in the mentor population and the trainee population will satisfy the intent of this NCI **requirement**. The description should clearly show how the purpose and objectives of the Program will meet the broader objectives and intent of the NCI to prepare candidates who can design and implement all phases of clinical trials research and and who can effectively participate in translational research projects involving clinicians and basic scientists.

b. Description of the **Core Requirements** of the Program: Describe the core **research** (e.g., basic and clinical), **hands-on** (e.g., protocol development; preparation of IRB applications, informed consent, clinical trials management including patient accrual, analysis of outcomes) and **didactic experiences** (e.g., biostatistics, clinical trials design) that each trainee must satisfy in order to complete the core requirements of the Program. In satisfying the core requirements, describe how individualized trainee career development plans will be developed that take into account past experiences and competencies before providing new experiences and skills provided by Program. Describe any certification, degree or other form of recognition, if any, that trainees will receive after completing the core requirements.

c. Research base/Resources and Facilities/Mentors (See Appendix for a suggested format for presenting the requested information):

Research: Describe the existing funded laboratory and patient-oriented research activities and the interactive nature of the research environment that will meet and sustain the needs and objectives of this career development Program.

Resources and Facilities: Describe the research infrastructure, patient populations, facilities etc. that are available and accessible to this career development Program,

Mentors: Describe the pertinent research experience and track record in training cancer clinician scientists of each mentor participating in the Program.

d. Program Management:
   1. **Program Leader:** Describe the qualifications and role of the Program Leader to provide leadership and coordination of the Program.

   2. **Recruitment Strategies:** Describe the selection criteria for candidates recruited to this Program. Describe the various strategies that will be used to ensure that the different clinical oncology disciplines represented by this Program are included and to ensure an adequate candidate pool size. Note the size of the candidate pool expected. Address the nature of any other competing institutional Programs that might limit the number of candidates and describe strategies for addressing this competition. Describe plans for recruitment of under-represented minorities (i.e., African Americans, Hispanic Americans, native pacific islanders, native Americans and Alaskans)and how these strategies will be implemented.

   3. **Advisory Committee:**
      Describe how the AC will function in providing oversight of the development, implementation and evaluation of recruitment strategies; in the recruitment and selection of candidates; in the evaluation of special curricula and/or links to curricula developed through a K30 grant, if such a grant exists in the institution; interim monitoring and evaluation of **each candidate's progress** with recommendations for changes in the training plan, if necessary, or termination of

a candidate who is not making adequate progress; and monitoring of the overall effectiveness of the Program.

4. **Individual Training Plans:** Provide **brief summaries** of the individual training plans that the Program will employ or has been able to achieve (Required for Competing Renewal Applications) in preparing candidates to design, implement and participate in patient-oriented cancer research and collaborate effectively with a basic scientists in translational research.

9. Summary Information on the Program. Sample tabular formats are provided for your convenience. "Click on" TABLES (Word for Windows) or TABLES (Word Perfect), which ever you prefer, to download this information.

10. Human Subjects: follow instructions provided in the Form PHS 398 application package;

11. Vertebrate Animals: follow instructions provided in the Form PHS 398 application package;

12. Appendices: follow instructions provided in the Form PHS 398 application package.

ANNUAL PROGRESS REPORT/APPLICATION FOR **CONTINUATION**

A. Submission of the Annual Progress Report and Application for Continuation:

The Program Leader/ Principal Investigator of an active **K12** grant is required to submit on an annual basis an application for continuation of funding. This continuation application must contain descriptions of the progress made during the last year of support, the budget needs for the next year, and any major changes in personnel and objectives that occurred during the previous year of funding and are planned for the next year. The National Institutes of Health will mail the face page for this application together with return mailing label(s) to the principal investigator/program leader approximately **four months** prior to the anniversary date of the grant. Look for this notification; if you do not receive it, call the NIH Data Management Branch at (301) 435-0896. The applicant **must** submit the application at least **2 months** prior to the anniversary date of the grant. If for some reason time becomes an issue, contact the NCI (see XI. INQUIRIES).

Applications are to be submitted on the Application for Continuation Grant Form PHS 2590 (last revised, 4/98). This form can be obtained directly by "clicking on" the following NIH website address: http://grants.nih.gov/grants/funding/2590/2590.htm. Forms can also be found at the other sources noted above for competing applications.

Since the Form PHS 2590 does not apply easily to the **K12** grant, adapt the application for continuation Form PHS 2590 generally so it contains the following:

- Appropriate Face page A as instructed in the Form 2590
- A Budget page B in the Form 2590. Note the salary and fringe benefits for each trainee by name or by position. Note all other budgetary information (e.g., supplies, travel, etc.) by name or position.
- A brief description of the Objectives and Goals of the Program
- A brief summary listing by name which faculty, mentors, and Advisory Committee members have left the Program and which new individuals are taking their places. Include for each person their degree and department affiliation (or equivalent).
- Biographical sketches of
    i. New faculty
    ii. New mentors
    iii. New Advisory Committee Members
    iv. New Trainees

- Progress of Individual Trainees: A brief paragraph for each trainee describing the research and didactic experiences ongoing and completed, as well as specific future plans, for satisfying the Core Requirements of the Program.
- List of publications for each trainee resulting from their work in the Program.
- Summary Information of the Program: Sample tabular formats for provided are provided for your convenience. "Click on" TABLES (Word for Windows) or TABLES (Word Perfect), which ever you prefer, to download this information.
- A Report from the Advisory Committee (AC)that is separately attached summarizing the actions or the AC during the last year, evaluating the performance of the Program in meeting its objectives and the intent of the NCI, evaluating the effectiveness of recruitment strategies (provide a separate evaluation for minority recruitment), and providing recommendations for improving the Program (e.g, new mentors, changes in core requirements, changes in recruitment strategies etc.)

VIII. REVIEW PROCEDURES AND CRITERIA:

A. Review Procedure:

Upon receipt, applications will be reviewed initially by both CSR and the NCI for completeness and for conformance to all eligibility requirements (see section **III. ELIGIBILITY** above) and special provisions and requirements (see section **VI. SPECIAL PROVISIONS AND REQUIREMENTS** above). Applications that are incomplete or ineligible or that obviously do not meet the special provisions and requirements of the Clinical Oncology Research Career Development Program will be returned without further consideration.

Those applications judged to be both complete and responsive will be further evaluated according to the review criteria stated below for scientific and technical merit by a standing peer review group convened by the *Division of Extramural Activities* (http://deainfo.nci.gov/extra/dea.htm) in the NCI. This review group will be specialized in evaluating patient-oriented research and will assign a score (i.e., priority score) to each application based on the merit of the application. Applications will receive a second level review by the National Cancer Advisory Board (NCAB) to determine if the application meets the broad program needs and priorities of the NCI and the National Cancer Program.

B. Review Criteria:

1. Purpose and Objectives:
    - adequacy in representing the required **two or more** oncology disciplines among the mentors and in the trainee population.
    - clarity of the Program's objectives
    - adequacy in meeting the NCI intent to prepare candidates who can design and implement all phases of clinical trials research and effectively lead a translational research project involving clinician and basic scientists.
    - track record of the institution in the development of trainees as productive independent clinician investigators
    - adequacy of the commitment of the institution assuring that candidates will spend a a minimum of 75% of a full-time professional effort in research or research-related career development.
2. Core Requirements:
    - quality of the process for evaluating each candidate's need relative to all core didactic and core research training requirements.
    - adequacy of the nature and duration of the basic and clinical research requirements
    - adequacy of the nature and duration of specialized core didactic training/curriculum (e.g., biostatistics, clinical trails design, informed consent)
3. Research base/Resources and Facilities/Mentors:
    - adequacy of the funded research laboratory and patient-oriented research base to support a career development program.

- adequacy of the multi-disciplinary interactions present to provide the proper example of a translational research environment.
- adequacy of the available research infrastructure, access to technologies and methodologies, and patient populations. to support a career development program.
- quality of the mentors' research experience and productivity and their track records in training basic and patient-oriented research researchers.

4. Program Management
    - adequacy of the Program Leader's qualifications to lead and coordinate the Program recruitment
    - adequacy of the strategies for attracting and the criteria for selecting the best clinician candidates.
    - adequacy of the trainee pool to meet the needs of the Program.
    - adequacy of the strategies to recruit minorities.
    - appropriateness of the experience of the membership of the Advisory Committee (AC).
    - adequacy of the AC's involvement as a quality control in:
        i. selecting candidates for participating in the program
        ii. establishing appropriate training plans for each candidate based on the core requirements
        iii. monitoring the progress of candidates and making midcourse corrections to improve the quality of the candidate's experiences
        iv. terminating candidates for evident lack of performance or potential
        v. monitoring and evaluating the overall performance of the Program
    - The quality and completeness of the individual training plans relative to the core requirements and objective of preparing candidates who can design and and implement all phases of clinical trials research and effectively lead a translational research project involving clinician and basic scientists.
    - Adequacy of the proposed means for protecting human subjects and vertebrate animals against hazardous or unethical research procedures and for protecting the privacy of human subjects.
    - (For competing renewal applications): Quality/success in achieving the research career development objectives of this Program and meeting the NCI's intent
    - Appropriateness of the budget to achieve the objectives of the Program as proposed.

IX. AWARD CRITERIA:

Soon after the National Cancer Advisory Board approves the application, NCI staff will notify the applicant of his/her funding status. Awards are made based on the availability of funds each fiscal year, the scientific merit of the application as judged by peer reviewers, and the program priorities of the National Cancer Institute.

X. QUESTIONS AND ANSWERS

1. How many trainees can be supported by a **K12** grant?

   As many as can be accommodated by the $700,000 cap on each **K12** grant, and by the resources available to the program.

2. Can the support provided for OTHER EXPENSES be used to offset costs incurred in advertising and recruiting for the program?

   No. The OTHER EXPENSES are to be used **only** to partially support supplies, equipment, travel, and other expenses related to an individual trainee's individual career development.

3. Who should be on the Advisory Committee?

The **K12** program requires representation by each oncology discipline participating in the program. The individual members of the committee should be **K12** program faculty, preferably with well-established grant supported programs and with a substantial track record in training the types of individuals who will be appointed to the **K12** program.

4. Since human subjects are to be involved in every **K12** program, must each trainee obtain his/her own Institutional Review Board (IRB) approval?

   No, if the trainee will be participating in a larger research program that already has received IRB approval.. Yes, if the research proposed is not part of an ongoing research project with an IRB approval.

5. Is there a preference in the oncology disciplines represented in the **K12** program?

   No. The only requirement is that at least 2 oncology disciplines must be represented in the program.

6. Can I assign a trainee to a laboratory project with a basic research component?

   Yes. However, this should not comprise a major proportion of the total planned research experience of the trainee; and the basic research component ideally would be integrated with the patient-oriented clinical research project. The actual assignments of trainees will depend on prior experience. For example, if a trainee has already had significant laboratory/basic research experience, then there is no reason to provide more of this experience as part of the **K12.**

7. Can the trainee's salary be supplemented?

   Yes, but only from non-PHS sources and if there is no requirement for additional work. A trainee can be compensated for work while receiving salary from the **K12** grant. However, the percent effort committed to this work cannot exceed 25 percent of full-time professional effort.

8. When is the next announcement of the K12 program?

   Applications were previously solicited through an RFA. The **K12** program is now being announced as a Program Announcement with a once-a-year June 1 submission date.

9. Will my grant application be reviewed by a CSR study section?

   No. Applications for the NCI Institutional Clinical Oncology Career Development Program (**K12**) are reviewed by an NCI peer review group that is particularly sensitive towards training and career development needs in patient-oriented and translational cancer research.

10. Can a **K12** grant be awarded for less than 5 years?

    No. The length of the award is 5 years.

11. What are the **K12** requirements for training in responsible conduct of research?

    K12 grants does not have any mandatory requirements. However, it is strongly recommended that trainees deficient in this area obtain training in the responsible conduct of research.

12. Are there preferred formats for the tables requested in the grant application?

    Yes. The NCI has made available suggested formats for organizing the requested data. Use of these formats is encouraged in order to make the applications standard and assist the review

process. ("Click on" TABLES (Word for Windows) or TABLES (Word Perfect), which ever you prefer, to download this information.)

13. Does the NCI **K12** grant operate under Expanded Authority?

    Yes. However, automatic carryover of unexpended funds is not permitted. If there is a need for carryover prior approval by NCI Grants Administration Staff is required. Under most circumstances, each K12 is fully funded each year and there is little need for carryovers.

14. Is it possible to provide an additional position to a **K12** grant for a member of an ethnic group that is underrepresented in biomedical research ?

    Yes. The Principal Investigator may apply for a minority supplement to the **K12** grant. The Program Director of the **K12** grant should contact the NCI Comprehensive Minority Biomedical Branch (CMBB) for information on these supplements. The CMBB can be reached at the following website address: http://deainfo.nci.nih.gov/cmbs/index.htm.

15. If I have a K12 award and I would like to ask for post award changes? How do I go about this?

    You must contact the NCI Grants Administration official to determine the appropriate procedures to use in making a request for post award changes in your grant. This also applies to any of your needs that require a prior approval from the NCI. In general, you will have to make a request that is signed by you and a business offical of your institution. After receiving the request, the Grants Administration offical will consult with the NCI scientific program staff as necessary to determine whether the request can be approved.

XI. INQUIRIES (K12):

We have tried to provide you with the most complete information possible about the **K12**, as well as answer the most frequently asked questions. If you need information and explanation concerning the **K12**, please make your inquiries as follows:

A. Programmatic or scientific issues:

If you need more information and/or advice about the objectives and scope of this award, eligibility requirements, structure and organization of grant applications and peer review trends, please contact us by "clicking on" the INQUIRIES link directly below. You will be contacted promptly by one of the scientific professionals of the Cancer Training Branch of the NCI.

B. Fiscal Issues:

If you need information about the appropriate procedures for dealing with issues that involve changes in the sponsoring institution, the scope of the project as awarded, budget and period of support of the award or that involve any other issues requiring approval by the NCI or post award actions, please contact us by "clicking on" the INQUIRIES link directly below. You will be contacted promptly by one of the Grants Administration officials of the NCI.